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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,238	12/05/2001	Lawrence A. Shimp	525400-208	8543

7590 06/12/2003

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EXAMINER	
WILLSE, DAVID H	
ART UNIT	PAPER NUMBER
3738	6

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/005,238	Applicant(s) SHIMP ET AL.
	Examiner Dave Willse	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-138* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1:	Figures 1-4;
Species 2:	Figure 5;
Species 3:	Figures 6 and 7;
Species 4:	Figure 8;
Species 5:	Figure 11;
Species 6:	Figure 12;
Species 7:	Figures 34 and 37;
Species 8:	Figure 35;
Species 9:	Figures 36 and 38;
Species 10:	Figure 39;
Species 11:	Figure 42;
Species 12:	Figure 43;
Species 13:	Figure 44;
Species 14:	Figure 45;
Species 15:	Figure 46;
Species 16:	Figure 47;
Species 17:	Figure 48;
Species 18:	Figures 49-51;
Species 19:	Figure 52;
Species 20:	Figures 53 and 54;

Species 21: Figure 62;

Species 22: Figure 63;

Species 23: Figure 64;

Species 24: Figure 65;

Species 25: Figure 66;

Species 26: Figure 67;

Species 27: Figure 71;

Species 28: Figure 72;

Species 29: Figures 73 and 74;

Species 30: Figure 75;

Species 31: Figure 76;

Species 32: Figures 77 and 77a;

Species 33: Figure 78;

Species 34: Figures 90-93;

Species 35: Figure 94a;

Species 36: Figure 94b;

Species 37: Figures 95-98.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable**

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species (MPEP § 809.02(a)).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-34, 58-87, 114-122, 127, and 128, drawn to an implant, classified in class 623, subclass 17.11.

II. Claims 35-57, drawn to a pin, classified in class 623, subclass 23.63.

III. Claims 88-113, 123-126, and 129-131, drawn to a method for forming an implant, classified in class 264, subclass 239+.

IV. Claims 132-138, drawn to a method of forming a bone pin, classified in class 264, subclass 299+.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require

the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the "cortical bone having a fiber direction", "sections which are offset relative to each other", and so on (instant claim 35) are not required for the combination. The subcombination has separate utility such as in connecting two natural bone fragments together or in anchoring a prosthetic joint component into bone.

Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the "cutting dies of progressively smaller bore sizes" (present claim 132) are not required in combination method claims. The subcombination has separate utility such as in forming pins for bone fractures or other attachment needs.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as by molding and/or directed bone tissue growth procedures (via a scaffold, for example) or by well known

plastic or metal manufacturing processes (since many of the implant claims are not even limited to bone materials).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent required searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is (703) 308-2903. The supervisor, Corrine McDermott, can be reached at (703) 308-2111. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse
June 6, 2003

DAVE WILLSE
PRIMARY EXAMINER
ART UNIT 3738